

REMARKS

Claims 1-3, 8-15, 17-20, and 22-32 are pending and at issue. Claims 1, 18, 19, and 27 have been amended. Claim 1 has been amended to specify that X is an O or S atom; and claims 18 and 19 have been amended to specify that the linker is bonded to the agent via an O or S atom of the linker. Support for these amendments is found in the specification at, for example, page 5, lines 9-10; page 15, lines 5-8; and in original claim 1. Claim 27 has been amended to remove language regarding the group containing one or more O, N, or S atom. Support for this amendment is found in original claim 4. No new matter has been added. Reconsideration of the application is respectfully requested.

Request for Withdrawal of Finality of Office Action

Applicants respectfully request that the Examiner withdraw the finality of the July 11, 2005 Final Office Action and enter the present amendment as it is believed to place the pending claims in condition for allowance or in better form for appeal. The July 11, 2005 Final Office Action is the first Office Action in which the correct pending claims have been examined in view of the correct specification (International Application No. PCT/US00/04140).

“The U.S. Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (citing *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (emphasis added)). Therefore, the rejections set forth in the July 11, 2005 Office Action constitute a first office action on the merits of the claims in this application, and the finality of this Office Action should be withdrawn.

Rejections Under 35 U.S.C. §103(a)

Claims 1-3, 8-15, 17-20, 23, 24, 27, and 32 have been rejected under 35 U.S.C. §103(a) as obvious over Chasalow (U.S. Patent No. 5,830,432) ("Chasalow"). Chasalow discloses conjugates in which a carboxy-containing therapeutic agent is attached to a phospholipid via an amino alcohol linking moiety. *See* col. 1, lines 4-8, 55-64; and col. 2, lines 38-41. According to the Examiner, it would have been obvious to attach the alcohol group of the therapeutic agent to the carbonyl group of the amino alcohol linking moiety.

Claim 1 has been amended to specify that X is an O or S atom; and claims 18 and 19 have been amended to specify that the linker is bonded to the agent via an O or S atom of the linker. Thus, the presently claimed compounds call for an O or S atom to be present between the agent and the linker. Accordingly, the present compounds do not comprise an amide bond formed between a carbonyl group of the therapeutic agent and a nitrogen atom of the linker because the present claims do not call for a N atom to be present between the agent and the linker.

In contrast, Chasalow discloses only two types of conjugates: those that do not have linkers and those that require amide bonds. In the Chasalow conjugates without linkers, the alcohol-containing agent is directly attached to the phospholipid. *See, e.g.*, cols. 9-10; and col. 11 (last structure). There is no teaching or suggestion in Chasalow that would have motivated one of ordinary skill in the art to modify these compounds by inserting a linker (as required by the presently pending claims) between the therapeutic agent and the phospholipid and having the particular points of attachment called for in the pending claims.

The remaining Chasalow conjugates require an amide bond formed between the carbonyl group on the agent and the free amino group on the linker. *See, e.g.*, cols. 5-6 (last structure); cols. 7-8 (last structure). These conjugates are credited with increasing the water solubility and

bioavailability of the therapeutic agent. *See* col. 1, lines 4-8; and col. 2, lines 43-46. The amide bond is a key feature of the conjugate and is the point at which the target drug may be cleaved by a peptidase from the linker-phosphocholine moiety. *See* col. 2, lines 52-57; col. 4, lines 1-28.

The Examiner states that, in view of Chasalow, it would have been obvious to attach a therapeutic agent to the carbonyl group on a linker-phosphocholine moiety. However, Chasalow does not teach or suggest attachment of the agent to a carbonyl group on the linker, if such a group is even present. Rather, the key points of attachment on the Chasalow linkers are the alcohol and amino groups. Furthermore, one of ordinary skill would not have been motivated to make a conjugate using a linker that did not form an amide bond (as called for in the presently pending claims) because the main purpose of using a linker in Chasalow is to obtain the benefits afforded by the amide bond (i.e., bioavailability, solubility, and ease of cleavage).

In view of the foregoing, claims 1-3, 8-15, 17-20, 23, 24, 27, and 32 are not obvious over Chasalow, and this rejection should be withdrawn.

Allowable Subject Matter

The Examiner is thanked for indicating that claims 26 and 31 are allowable, and that claims 22, 25, 26, and 28-31 would be allowable if rewritten in independent form. Claims 25, 26, and 31 are independent claims and thus do not require amendment to be in independent form. Accordingly, claims 25, 26, and 31 should be allowed. Claims 22 and 28-30 remain in dependent form because the rejection of their respective base claims has been overcome in view of the above amendments and remarks.

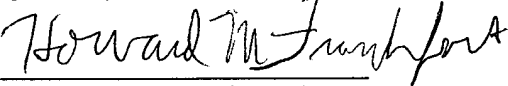
Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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